UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE BIOZORB DEVICE PRODUCTS LIABILITY LITIGATION	*	
	*	Civil Action No. 1:22-cv-11895-ADB
This Order Relates To: 1:23-cv-10599-ADB	*	

MEMORANDUM AND ORDER

BURROUGHS, D.J.

Before the Court is Defendant Hologic's motion for summary judgment on Plaintiff Pamela Gibson's ("Plaintiff" or "Gibson") claim that Hologic's alleged failure to warn her breast-cancer surgeon about certain risks associated with the BioZorb, a radiographic marking device, caused her to suffer a variety of injuries. [ECF No. 83 ("Motion" or "Mot.")].[1] Gibson, as well as more than eighty other individual plaintiffs spread across twenty-three cases before this Court, alleges that Hologic breached tort and contractual duties in its design and marketing of the BioZorb. In support of the pending summary judgment motion, Hologic contends that the undisputed facts foreclose any reasonable jury from finding that Hologic's failure to warn about risks associated with the BioZorb proximately caused Gibson's injuries. See [ECF No. 84 ("Memorandum" or "Mem.")]. For the following reasons, Hologic's motion is **GRANTED IN PART** and **DENIED IN PART**.

[1] Unless otherwise specified, all citations to the record refer to Civil Action No. 1:23-cv-10599.

I. BACKGROUND

A. Factual Background

The BioZorb marker is an implantable medical device approved by the Food and Drug Administration ("FDA") as a Class II medical device indicated for situations where an excision site needs to be marked for future medical procedures, like radiation treatment. See, e.g., [ECF No. 104-1 ("Responsive Statement of Undisputed Facts" or "RSUF") ¶¶ 1–3]. The BioZorb consists of a spiral-shaped bioabsorbable spacer that holds permanent titanium clips. [Id. ¶ 2]. Although BioZorb markers come in a range of sizes, the parties agree that the image below accurately depicts an example configuration of the device.

[Id.] The device is intended to dissolve into the body during a process Hologic calls "resorption," leaving behind titanium clips that allow for radiographic targeting. [Id. ¶ 4].

According to the BioZorb's Instructions for Use in effect at the time of Gibson's operation, the resorption process may take "one or more years." [ECF No. 104-5 ("IFU")]. Specifically, the IFU advised that "the spacer material retains its functional integrity for approximately [two] months, while complete resorption may require up to one or more years." [Id.] The IFU expressly warns of the following risks and contraindications:

> The Marker should not be placed in a tissue site with clinical evidence of infection . . . . The marker should only be used by

> physicians trained in surgical techniques. The physician is responsible for its proper clinical use. The Marker is shipped sterile; do NOT re-sterilize any portion of the Marker. The Marker is for SINGLE USE only. Do NOT use if the package is open or damaged, or if the temperature indicator has a black center. Use the Marker prior to the expiry date shown on the product label.

[Id.]

Gibson is a citizen of Colorado. [ECF No. 86-2 ("Gibson Dep.") at 12:3–8]. After Gibson was diagnosed with breast cancer in April 2020, [RSUF ¶ 5], on June 1, 2020, Dr. Laura Pomerenke performed a partial mastectomy on Gibson's right breast and a sentinel lymph node biopsy at UCHealth Memorial Hospital North in Colorado Springs, [RSUF ¶ 6]. During surgery, Dr. Pomerenke implanted a BioZorb in Gibson's right breast. [Id.] After it was determined that some cancerous tissue remained in her breast and lymph nodes, [ECF No. 86-1 ("Pomerenke Dep.") at 44:2–45:16], Gibson underwent a second procedure to remove additional tissue, and the BioZorb was left in place. [Id. at 48:20–22].[2] In a deposition taken in connection with the instant motion, Gibson testified that after her surgery, she experienced pain and a lump that feels like a "rock" in her chest. [Gibson Dep. at 90:13–92:13].

Dr. Pomerenke, a since-retired board-certified general surgeon specializing in breast cancer surgery, was deposed on June 13, 2024 in connection with this case. [Pomerenke Dep. at 10:15–11:1]. Dr. Pomerenke testified that she had used the BioZorb about "a dozen times," [id. at 23:17–24], between early 2020 and her retirement, [id. at 27:3–6, 74:3–6]. She explained that she used the BioZorb as part of post-lumpectomy oncoplastic treatment because she believed the device would "g[ive] the radiation doctor a smaller target," which "reduces the amount of

[2] Dr. Pomerenke "resuture[d] the BioZorb to the breast tissue," but found no reason "to remove the BioZorb" at that time. [Pomerenke Dep. at 49:3–8].

radiation that's used" following treatment. [Id. at 25:21–26:7]. Dr. Pomerenke testified that she found the BioZorb to be a useful tool in appropriate cases. [Id. at 24:1–5].

Dr. Pomerenke first noticed post-surgical symptoms in Gibson during a June 2021 physical examination, during which she observed that Gibson had begun to develop mild lymphedema and "[radiation] fibrosis at her lumpectomy site." [Pomerenke Dep. at 54:13–18, 55:21–56:1]. Dr. Pomerenke noted that the fibrosis was causing Gibson to "struggl[e] with right breast pain following her lumpectomy and radiation." [Id. at 56:12–14]. Dr. Pomerenke continued to observe fibrosis during subsequent exams. [Id. at 58:14–18, 59:13–16, 61:8–13, 62:13–16]. Although the radiation fibrosis site was located near where she implanted the BioZorb, Dr. Pomerenke testified that she did not believe that the fibrosis was caused by the BioZorb, [id. at 62:17–24], nor did the fibrosis cause her to "second-guess [her] treatment decision to use" the BioZorb in Gibson's treatment, [id. at 69:4–8]. Dr. Pomerenke also testified that she did not see evidence that the BioZorb had migrated or otherwise failed to resorb, [id. at 65:15–22], explaining that "[f]rom [Gibson's] mammogram, you c[ould] see that the markers were in place, but there was no evidence that they had moved or dispersed or anything else," [id. at 65:19–22].

B. Relevant Procedural History

Gibson and four co-plaintiffs filed this lawsuit against Hologic on March 17, 2023, [ECF No. 1], and have amended their complaint twice. [ECF Nos. 131, 138]. The operative complaint asserts four causes of action: Negligence for Failure to Warn (Count I), Negligence for Design Defect (Count II), Breach of Implied Warranty of Merchantability (Count III), and Negligence (Count IV). [ECF No. 138 ("Second Amended Complaint" or "SAC")].

The Court's case management orders allow phased discovery and summary judgment proceedings. [ECF Nos. 11, 12]. The first phase of discovery is limited to core document discovery and depositions of plaintiffs and their implanting physicians, in order to allow for summary judgment motions regarding the application of the learned intermediary doctrine to the causation element of each plaintiff's failure-to-warn claim. See [ECF No. 11 at 3]. Accordingly, Hologic filed a motion for summary judgment based on the learned intermediary doctrine on June 28, 2024. [Mot.; Mem.]. Gibson opposed on July 29, 2024, [ECF No. 104 ("Opp.")], and Hologic replied on August 12, 2024, [ECF No. 121 ("Reply")]. The parties have chosen Gibson as one of four bellwether trial plaintiffs.[3]

II. DISCUSSION

A. Legal Standard

A movant may obtain summary judgment only by showing "that there is no genuine dispute" between the parties "as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party must first show "an absence of evidence to support the nonmoving party's case." Pleasantdale Condos., LLC v. Wakefield, 37 F.4th 728, 733 (1st Cir. 2022) (quoting Brennan v. Hendrigan, 888 F.2d 189, 191 (1st Cir. 1989)). "This burden can be satisfied in two ways: (1) by submitting affirmative evidence that negates an essential element of the non-moving party's claim or (2) by demonstrating that the non-moving party failed to establish an essential element of its claim." Nantucket Residents Against Turbines v. U.S. Bureau of Ocean Energy Mgmt., 675 F. Supp. 3d 28, 46 (D. Mass. 2023) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 331 (1986)). "The burden then shifts to the

[3] See [Case No. 1:22-cv-11895, ECF No. 201].

nonmovant to establish the existence of a genuine issue of material fact." Pleasantdale, 37 F.4th at 733. The Court must construe "the record and all reasonable inferences therefrom in the light most hospitable" to the nonmoving party. See id. (quoting Houlton Citizens' Coal. v. Town of Houlton, 175 F.3d 178, 184 (1st Cir. 1999)).

Still, the Court will not let cases go to trial based only on a nonmovant's "bald assertions, empty conclusions, or rank conjecture." Hoover v. Hyatt Hotels Corp., 99 F.4th 45, 57 (1st Cir. 2024) (citation and alteration omitted). Instead, where (as here) "the nonmovant bears the ultimate burden of proof" concerning the issue on which summary judgment is sought, the nonmovant "must present definite, competent evidence to rebut the motion for summary judgment." Pleasantdale, 37 F.4th at 733 (quoting Mesnick v. Gen. Elec. Co., 950 F.2d 816, 822 (1st Cir. 1991)).

B. Count I

Because Gibson's injuries occurred in Colorado, the state of her domicile, the Court will apply Colorado law to her claims, consistent with its earlier rulings on conflict of laws related to BioZorb litigation. See, e.g., In re BioZorb Device Prod. Liab. Litig., No. 1:22-cv-11895, 2025 WL 27628, at *4 (D. Mass. Jan. 3, 2025). On a failure-to-warn claim under Colorado law, the plaintiff bears the "burden of proving that the manufacturer gave an inadequate warning of the danger that caused the [plaintiff's] injury." O'Connell v. Biomet, Inc., 250 P.3d 1278, 1281 (Colo. Ct. App. 2010). Colorado courts apply the learned intermediary doctrine "to failure to warn claims in the context of a medical device . . . when [the device] is available only to physicians and obtained by prescription, and the doctor is in a position to reduce the risks of harm in accordance with the instructions or warnings." Id. at 1281–82. Under Colorado law, Hologic's "duty to warn [is] limited to an obligation to advise the prescribing physician of any

potential dangers that may result from the [BioZorb]'s use." Id. at 1281. Colorado does not apply a heeding presumption in failure-to-warn cases,[4] at least as to "obviously dangerous" products. See Pothoff v. Alms, 583 P.2d 309, 311 (Colo. Ct. App. 1978).

The parties agree that because only the causation element is presently before the Court, the sole question to be decided at this point is whether the record creates a genuine dispute of material fact as to whether an adequate warning would have altered Dr. Pomerenke's decision to use the BioZorb and thereby prevented Gibson's injuries. Because Gibson carries "the ultimate burden of proof" on causation, Pleasantdale, 37 F.4th at 733, she "must produce evidence that [Dr. Pomerenke] would not have used the BioZorb had the manufacturer provided adequate warnings." In re BioZorb Device Prod. Liab. Litig., No. 1:22-cv-11895, 2024 WL 4309413, at *14 (D. Mass. Sept. 26, 2024). The failure to point to a triable question of fact as to causation would prove fatal to her claim. See id. (granting summary judgment as to plaintiff Nerissa Burke).

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[4] Plaintiff passingly suggests that Colorado law applies a heeding presumption — i.e., that under Colorado law, courts will presume that "[w]here a warning is given, it is assumed that it will be read and heeded." [Opp. at 11 n.6 (quoting Campbell by & Through Campbell v. Burt Toyota-Daihatsu, 983 P.2d 95, 97 (Colo. App. 1998) (citing Restatement (Second) of Torts § 402A cmt. j (Am. L. Inst. 1965)))]. As Defendants point out, however, Colorado courts do not "constru[e] Comment j to create a special presumption concerning proximate causation." Pothoff, 583 P.2d at 311; see also [Reply at 3 n.2]. As applied in Colorado, the Restatement's provision "charge[s]" the recipient of a warning "with notice of [the warning's] contents," regardless of whether the recipient actually read it," Campbell, 983 P.2d at 97, but it does not shift the burden of production between the parties. Cf. In re Fosamax Prod. Liab. Litig., 688 F. Supp. 2d 259, 266 (S.D.N.Y. 2010) (citing Ortho Pharm. Corp. v. Chapman, 388 N.E.2d 541, 555 n.12 (Ind. Ct. App. 1979) (requiring defendant to produce "evidence that an adequate warning would not have been heeded" to rebut heeding presumption under Indiana law). Consequently, whether Dr. Pomerenke "would have acted in the same manner had a proper warning been given is normally a question of fact . . . which a jury," or (as here) the Court ruling on summary judgment, must consider "unaided by presumptions and guided only by the evidence before it." Pothoff, 583 P.2d at 311.

Here, the summary judgment record lacks evidence that could carry even this modest burden. Gibson's counsel never questioned Dr. Pomerenke at her deposition as to whether a stronger warning would have changed her decision to use the BioZorb, nor does the record otherwise contain evidence that would permit a jury to so conclude. To be sure, her attorney elicited testimony that Dr. Pomerenke was unaware of a variety of potential risks associated with the BioZorb. See, e.g., [Pomerenke Dep. at 81:5–21, 106:3–6 (discussing Pomerenke's limited knowledge about prolonged resorption risk)]; [id. at 105:3–23 (same, regarding risk of pain)]. But such testimony cannot carry her burden at summary judgment, as it says nothing about the critical question on the issue of causation: that is, what Dr. Pomerenke would have done if she had known of those risks.[5] See In re BioZorb Device Prod. Liab. Litig., No. 1:23-cv-10579, 2025 WL 369837, slip op. at *4 (D. Mass. Feb. 3, 2025). On that score, Dr. Pomerenke's testimony makes clear that she attributes Gibson's injuries to radiation fibrosis, a surgical complication that Dr. Pomerenke does not believe is related to the BioZorb, and that she stands by her decision to use the BioZorb in Gibson's surgical treatment. Gibson has pointed to no evidence that would permit a jury to find in her favor on that question, nor does the Court's independent review of the Pomerenke deposition reveal any. Consequently, "there can be 'no genuine issue as to any material fact,' since a complete failure of proof concerning an essential

[5] Gibson parenthetically refers to a Colorado case denying summary judgment on a failure-to-warn claim based on a doctor's testimony about surgical mesh, which Gibson contends bears close analogy to the facts here. [Opp. at 12 n.8 (citing Shostrom v. Ethicon, Inc., No. 20-cv-01933, 2021 WL 778994, at *5 (D. Colo. Mar. 1, 2021))]. Critically, however, the physician's testimony in that case permitted a jury to conclude that a warning would have led the physician to "share [the risk] information with [the plaintiff], and [that] the information could have affected his decision on what treatments to recommend to her." Shostrom, 2021 WL 778994, at *5. Similar testimony is absent from Dr. Pomerenke's testimony.

element of the nonmoving party's case necessarily renders all other facts immaterial."[6] Celotex, 477 U.S. at 317. Because Gibson has failed to identify a genuine dispute of material fact as to causation on her failure-to-warn claim, summary judgment on Count I is **GRANTED**.

C. Counts II, III, and IV

Hologic further contends that Gibson has inadequately pleaded her second count, a design-defect claim, by, among other things, failing to identify any "specific defects in the design of the BioZorb." See [Mem. at 1–2]. These arguments are unrelated to the learned intermediary doctrine, and, therefore, they fall outside the limited scope of the summary judgment filings permitted at this stage under the Court's case management orders. In any event, as the Court allowed the plaintiffs in these cases to amend their design defect claims and Hologic to file a separate motion to dismiss, which is now fully briefed, see [Case No. 1:22-cv-11895, ECF Nos. 190–91, 193, 200], the Court hereby **DENIES** without prejudice Hologic's motion for summary judgment as to Gibson's design-defect claim.

To the extent Hologic seeks summary judgment on Counts III and IV based on the learned intermediary doctrine, summary judgment is **GRANTED IN PART** to the extent such claims are premised on a failure to warn and **DENIED IN PART**, to the extent such claims are premised on a design defect theory of liability. See In re BioZorb, 2024 WL 4309413, at *14.

III. CONCLUSION

For the foregoing reasons, the motion is **GRANTED IN PART** and **DENIED IN PART**.

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[6] Gibson raises conclusory challenges to Dr. Pomerenke's credibility unsupported by specific record facts. [Opp. at 13–14]. She points, however, to no Colorado case supporting why her generic "challenge to the credibility of the movant's witness without any supporting evidence" should "create a genuine issue of material fact." Moreau v. Local Union No. 247, International Brotherhood of Firemen & Oilers, 851 F.2d 516, 519 (1st Cir. 1988). This argument therefore provides no footing for allowing her failure-to-warn claim to survive summary judgment.

SO ORDERED.

February 12, 2025

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE